UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

MELANIE MONTAGNON,	:	
Plaintiff,	:	
	:	
v.	:	**CIVIL ACTION NO.**
	:	**3:06-cv-00280 (VLB)**
PFIZER, INC.,	:	
Defendant.	:	**October 31, 2008**

MEMORANDUM OF DECISION GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT [Doc. #39]

The plaintiff, Melanie Montagnon, filed this action against Pfizer, Inc. ("Pfizer") for actual and punitive damages in Connecticut Superior Court pursuant to the Connecticut Product Liability Act, Conn. Gen. Stat. § 52-572m et seq. ("CPLA") on February 2, 2006 alleging that Pfizer's drug Depo-Provera Contraceptive Injection ("Depo-Provera") caused her to develop osteoporosis. Pfizer removed the action to this Court pursuant to 28 U.S.C. §§ 1441 and 1446. Jurisdiction is proper on the basis of diversity of citizenship under 28 U.S.C. § 1332(a)(1) because Pfizer is a Delaware corporation with a principal place of business in New York and Montagnon is a Connecticut resident who claims more than $75,000 in damages.

Pfizer has filed a motion for summary judgment claiming that there is no genuine issue of material fact and that it is entitled to a judgment as a matter of law. For the reasons hereinafter set forth, Pfizer's motion is GRANTED.

I. Facts

Examination of the affidavits, deposition transcripts, and exhibits attached to the motion for summary judgment and responses disclose the following undisputed material facts. Pfizer is a Delaware corporation headquartered in New York with research and development facilities located in Groton and New London, Connecticut. In 1992, Pfizer received approval from the Food and Drug Administration ("FDA") to begin selling Depo-Provera, a prescription contraceptive. As the manufacturer of a prescription medication, Pfizer was required to provide a package insert for the prescribing physician containing a "a summary of the essential scientific information needed for the safe and effective use of the drug." 21 C.F.R. § 201.56(a) (1991). From 1992 to 2004, the "Physician Information Section" of the package insert stated under the heading "WARNINGS":

> **2. Bone Mineral Density Changes**
> **Use of DEPO-PROVERA Contraceptive Injection may be considered among the risk factors for development of osteoporosis. The rate of bone density loss is greatest in the early years of use and then subsequently approaches the normal rate of age related fall.**

[Doc. #40, Exhibit D]. The "Patient Labeling" section of the package insert, which is designed to be shared with the patient, contained a subsection titled "Risks of Using DEPO-PROVERA Contraceptive Injection," which contained the additional warning:

> **2. Bone Mineral Changes**
> **Use of DEPO-PROVERA may be associated with a decrease in the amount of mineral stored in your bones. This could increase your risk of developing bone fractures. The rate of bone mineral loss is greatest in the early years of DEPO-PROVERA use but, after that, it**

begins to resemble the normal rate of age-related bone mineral loss. Id. The package insert cited "osteoporosis" in both its list of "adverse reactions" and its list of "other side effects." Id. These warnings remained unchanged until 2004.

In May 1996, at the age of 18, Montagnon visited Planned Parenthood of Connecticut ("PPoC") to obtain birth control. She began receiving Depo-Provera at approximate intervals of 13 weeks, at PPoC and the Visiting Nurses Association at Newport, Rhode Island.

In November, 2004, Pfizer revised Depo-Provera's package insert to contain a more prominent "Black Box Warning" to alert physicians and patients to the risks of the drug:

> **Women who use Depo-Provera Contraceptive Injection may lose significant bone mineral density. Bone loss is greater with increasing duration of use and may not be completely reversible.**
>
> **It is unknown if use of Depo-Provera Contraceptive Injection during adolescence or early adulthood, a critical period of bone accretion, will reduce peak bone mass and increase the risk of osteoporotic fracture in later life.**
>
> **Depo-Provera Contraceptive Injection should be used as a long-term birth control method (e.g., longer than 2 years) only if other birth control methods are inadequate (see WARNINGS).**

[Doc. #40, Exhibit J] On December 8, 2004, a doctor at PPoC told Montagnon to take a calcium supplement "because of the risk of osteoporosis secondary to [Depo-Provera]. [Doc. #40, Exhibit N at MM12-MM30]. On March 2, 2005, a PPoC doctor advised Montagnon to take a bone mineral density test. She returned twice thereafter for additional injections of Depo-Provera but during the

intervening 26 weeks she did not schedule the prescribed bone mineral density test.

On August 11, 2005, Montagnon took a bone mineral density test at PpoC. The test revealed that she had a bone mineral density score of -3.7 in her spine. On August 23, 2005, a nurse at PPoC called Montagnon to tell her that because her bone density score was consistent with osteoporosis, PPoC would no longer prescribe Depo-Provera for her. Montagnon never received another Depo-Provera injection and is currently under the care of an osteoporosis specialist for treatment of her osteoporosis.

II. Summary Judgment Standard

Summary judgment "should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The Court "construe[s] the evidence in the light most favorable to the non-moving party and . . . draw[s] all reasonable inferences in its favor." Huminski v. Corsones, 396 F.3d 53, 69-70 (2d Cir. 2004). "[I]f there is any evidence in the record that could reasonably support a jury's verdict for the non-moving party, summary judgment must be denied." Am. Home Assurance Co. v. Hapag Lloyd Container Linie, GmbH, 446 F.3d 313, 315 (2d Cir. 2006). "The moving party bears the burden of showing that he or she is entitled to summary judgment." Huminski, 396 F.3d at 69. "[T]he burden on the moving party may be discharged by 'showing'—that is pointing out to the district court—that

there is an absence of evidence to support the nonmoving party's case." PepsiCo, Inc. v. Coca-Cola Co., 315 F.3d 101, 105 (2d Cir. 2002). "If the party moving for summary judgment demonstrates the absence of any genuine issue as to all material facts, the nonmoving party must, to defeat summary judgment, come forward with evidence that would be sufficient to support a jury verdict in its favor." Burt Rigid Box, Inc. v. Travelers Prop. Cas. Corp., 302 F.3d 83, 91 (2d Cir. 2002).

III. Discussion

Pfizer argues that it is entitled to summary judgment because the learned intermediary doctrine alters its standard of care under the CPLA and that its warnings were adequate to notify physicians about the risks of the drug. Pfizer further argues that without expert testimony, Montagnon is unable as a matter of law to establish the inadequacy of the warning to physicians.

Montagnon responds that there is an issue of material fact as to whether Pfizer should have revised the warnings to include more information relating to osteoporosis. She argues that the following warnings should have been included in the package insert:

> **1) bone loss is greater with increasing duration of use and may not be completely reversible, 2) use of DPCI in adolescents or early adulthood will reduce peak bone mass and increase the risk of osteoporotic fracture in later life, 3) DPCI should be used for more than two years only if other birth control methods are inadequate, 4) use of DPCI may cause you to lose calcium stored in your bones and the longer you use DPCI the more calcium you are likely to lose, and 5) loss of calcium may cause weak, porous bones (osteoporosis) that could increase the risk that our bones might break, especially after**

menopause.

(the "proposed warnings"). [Doc. #46, p. 7] Specifically, she argues that the results of studies of Depo-Provera published in 1991,[1] ("the 1991 Study") and a study published in 1999,[2] ("the 1999 Study") should have been integrated into the warning. She argues that no expert testimony is required to establish the inadequacy of the product warnings, and that the 1991 Study and 1999 Study are sufficient evidence to support a jury verdict that the Depo-Provera warnings were inadequate.

To recover under the CPLA, Montagnon must show that Pfizer failed to give adequate warnings of the hazards of Depo-Provera, and that as a result, Montagnon was injured. Conn. Gen. Stat. § 52-572(q)(c). Pfizer argues that Connecticut recognizes the learned intermediary doctrine, which requires the ultimate user of a prescription drug to show that the warnings were inadequate as to a prescribing physician. In Vitanza v. Upjohn Co., 778 A.2d 829, 839 (Conn. 2001) the Supreme Court of Connecticut held that "the learned intermediary doctrine is part of our common law" and adopted Comment (k) to the Restatement (Second) of Torts § 402A. Comment (k) provides that "a manufacturer of an unavoidably unsafe product should not be held to strict liability for unfortunate consequences attending their use, merely because he has

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[1] **Dr. Tim Cundy, et al., Bone Density in Women Receiving Depot Medroxyprogesterone Acetate for Contraception, 303 BRITISH JOURNAL OF MEDICINE 13 (1991).**

[2] **Dr. Delia Scholes, et al., Bone Mineral Density in Women Using Depot Medroxyprogesterone Acetate for Contraception, 93 OBSTETRICS AND GYNECOLOGY 233 (1999).**

undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk." Id. Specifically applied to drugs, "adequate warnings to prescribing physicians obviate the need for manufacturers of prescription products to warn ultimate consumers directly." Vitanza, 778 A.2d at 836. Montagnon concedes that the learned intermediary doctrine applies in this case. Thus, if the risks of Depo-Provera were known to "the person best able to take or recommend precautions against the potential harm," then Pfizer is not liable for any harm arising from its use. Id. at 840.

The learned intermediary doctrine as applied in this case precludes Montagnon from recovering for any injuries sustained from use of Depo-Provera unless she can show that the warnings were inadequate as to prescribing physicians. Montagnon's expert, Dr. Erik Alexander, testified at his deposition that he was unable to offer an opinion as to the adequacy of the warnings to either physicians or consumers because he had not reviewed them. [Doc. #40, Exhibit P at 18:22-19:7]. Pfizer's expert likewise did not offer an opinion about the adequacy of the warnings.

Montagnon argues that the two studies she has submitted show that Pfizer should have changed its warnings as research on the drug developed. Montagnon further argues that because Pfizer's expert witness, Dr. Michelle Warren, admitted distributing the 1991 Study to her medical interns, a jury could draw an inference that the warnings were inaccurate without the inclusion of the results of the 1991 Study. Montagnon argues that the 1991 Study and 1999 Study

reveal that her five proposed warnings should have been included in the package insert. However, neither study recommends any change in the warnings. As to the warnings proposed by Montagnon, to the extent they are not evident from the package insert statement "[t]he rate of bone density loss is greatest in the early years of use and then subsequently approaches the normal rate of age related fall," or its explicit warning of a risk of osteoporosis, they are rebutted by the noncommittal conclusion of the 1999 Study that "more detailed prospective evaluation of the effects of [Depo-Provera] . . . on the rates of bone density change over time are needed to clarify . . . the degree to which it can be reversed." Indeed, all of the conclusions of the 1999 Study are hedged by the author's assertions that "the implications for future bone health need further study." Montagnon has neither explained which conclusions of the two studies yield the warnings she proffers, nor argued at which time it was incumbent upon Pfizer to change its warnings, nor attempted to rebut the studies that Pfizer attached to its motion for summary judgment which drew opposite conclusions from Montagnon's warnings before 2004. [Doc. #40, Exhibit H]. There is therefore no issue of material fact as to the adequacy of the warnings.

Pfizer also argues that without expert testimony, Montagnon cannot prove the inadequacy of its warnings. "Ordinarily, expert medical opinion evidence, based on suitable hypotheses, is required, when the subject-matter to be inquired about is presumed not to be within common knowledge and experience." Fane v. Zimmer, 927 F.2d 124, 131 (2d Cir. 1991). In Gold v. Dalkon Shield Claimants

Trust, No. B-82-383 (EBB), 1998 WL 351456 at *3 (D. Conn. Jun. 15, 1998) the court held that expert testimony was required to prove that a birth control device malfunctioned, and granted summary judgment where no expert testimony was offered, holding that "medical evidence relating to causes of injury to the human body is not normally considered to dwell within the common knowledge of a layperson." While Dr. Alexander testified as to causation between the drug and the plaintiff's injuries, there is no expert evidence with which the jury could assess the link between the warnings and the injuries suffered by the consumer.

Montagnon argues that under Salem v. United States Lines Co., 370 U.S. 31, 35 (1962) the Court should not require expert testimony where "jurors are as capable of comprehending the primary facts and of drawing correct conclusions from them as are witnesses possessed of special or peculiar training." However, neither the Court nor a lay jury is capable of assessing the credibility of the 1991 and 1999 Studies, synthesizing the results of the studies (which do not plainly state any of the proposed warnings), or comparing the results of these studies with other studies that came to contrary conclusions. The FDA, staffed by medical experts, frequently takes years to carefully consider the evidence gleaned from multiple studies and reports before approving the form of a final warning. To allow a lay jury to supercede the findings of the FDA on the basis of an incomplete record of the research on this drug would circumvent the entire drug approval process. Even if expert testimony were not required as a matter of law, the Court finds that no jury of laymen, on the basis of two studies alone,

which have not been interpreted by expert testimony, could reasonably decide that Pfizer should have rewritten its warnings at some undecided point in time before 2004.

Pfizer's motion for summary judgment [Doc. #39] is GRANTED. The Clerk is directed to CLOSE this case.

IT IS SO ORDERED.

/s/

Vanessa L. Bryant
United States District Judge

Dated at Hartford, Connecticut: October 31, 2008.